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## **Continuous interscalene analgesia with ropivacaine 0.2% versus ropivacaine 0.3% after open rotator cuff repair: the effects on postoperative analgesia and motor function**

Borgeat, A ; Aguirre, J ; Marquardt, M ; Mrdjen, J ; Blumenthal, S

**Abstract:** **BACKGROUND:** Interscalene analgesia is a recognized technique for the management of postoperative pain after major shoulder surgery. The most effective local anesthetic concentration in this setting is still controversial. In this study, we compared the analgesia and side effects of a continuous infusion of ropivacaine 0.2% and 0.3% administered through an interscalene catheter for the first 48 hours after surgery. **METHODS:** Eighty consecutive patients scheduled for elective open rotator cuff repair were randomized into 2 groups to receive a continuous infusion of either ropivacaine 0.2% or ropivacaine 0.3% for 48 hours at a rate of 14 mL/h through an interscalene catheter after a preoperative bolus of 40 mL ropivacaine 0.5% in all patients. Pain score (visual analog scale 0-100), intensity of motor block, quality of sleep during the first postoperative night, morphine consumption, side effects, and patient satisfaction were assessed by an anesthesiologist masked to treatment group. **RESULTS:** Total morphine consumption was significantly reduced in group 0.3% (12 vs 30 mg). Quality of sleep was significantly better in group 0.3% (4% vs 27% of awakening during the first postoperative night). Handgrip strength, visual analog scale scores, and side effects were similar in both groups. **CONCLUSION:** The use of ropivacaine 0.3% through an interscalene catheter for the first 48 hours after open rotator cuff repair provided a significant reduction of morphine consumption and a better sleep quality for the first postoperative night without increasing the intensity of motor block or side effects.

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**Continuous interscalene analgesia with ropivacaine 0.2 % versus  
ropivacaine 0.3 % following open rotator cuff repair:  
effects on postoperative analgesia and motor function**

**Short Title:** Different ropivacaine concentrations for interscalene catheter

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## **Background**

Interscalene analgesia is a recognized technique for the management of postoperative pain after major shoulder surgery. The most effective local anesthetic concentration in this setting is still controversial. The aim of this study was to compare the analgesia and side-effects of a continuous infusion of ropivacaine 0.2% and 0.3% administered through an interscalene catheter for the first 48 hours after surgery.

## **Methods**

Eighty consecutive patients scheduled for elective open rotator cuff repair were randomized into two groups to receive a continuous infusion of either ropivacaine 0.2% or ropivacaine 0.3% for 48 hours at a rate of 14 ml/h through an interscalene catheter after a preoperative bolus of 40ml ropivacaine 0.5% in all patients. Pain score (VAS 0-100), intensity of motor block, quality of sleep during the first postoperative night, morphine consumption, side-effects and patient satisfaction were assessed by an anesthetist masked to treatment group.

## **Results**

Total morphine consumption was significantly reduced in group 0.3 % (12 vs. 30 mg). Quality of sleep was significantly better in group 0.3 % (4% vs. 27% of awakening during the first postoperative night). Hand grip strength, VAS scores and side-effects were similar in both groups.

## **Conclusion**

The use of ropivacaine 0.3% through an interscalene catheter for the first 48 hours after open rotator cuff repair provided a significant reduction of morphine consumption, a better sleep quality for the first postoperative night without increasing the intensity of motor block or side effects.

## Introduction

Patient-controlled interscalene analgesia after shoulder surgery was shown to provide better pain relief and a higher degree of patient satisfaction compared to patient-controlled intravenous analgesia with opioids(1). Following major open shoulder surgery, ropivacaine 0.2% is associated with better preservation of strength in the hand and lesser paresthesias in the fingers than bupivacaine 0.15%, while providing comparable analgesia (2).

The influence of two different concentrations of ropivacaine used for perineural interscalene postoperative analgesia following open rotator cuff repair has not been reported. The aim of this study was to compare ropivacaine 0.3% versus ropivacaine 0.2% with regard to the quality of postoperative analgesia. We hypothesized better postoperative analgesia with similar degree of motor block in the hand and paresthesias in the fingers with ropivacaine 0.3% compared to 0.2%. The primary outcome was the postoperative intravenous morphine consumption 24 hours after the initial ropivacaine administration through the interscalene catheter.

## Material and Methods

After obtaining approval of the local ethical committee (Kantonale Ethikkommission, Gesundheitsdirektion des Kantons Zürich) and written informed consent, 80 adult patients of both sexes (classified as ASA physical status I-III, age 18-75 years, weight 50-100 kg) scheduled for elective open rotator cuff repair were included. Exclusion criteria before the study were severe bronchopulmonary disease, myocardial infarction within the last 6 months, haemostasis abnormality, known allergy to one of the trial drugs, known neuropathy or neurologic damage to the brachial plexus. Randomization was performed during pre-anesthetic preparation, the day before surgery. Patients were randomized according to a computer-derived list to receive either ropivacaine 0.3% (= group 0.3%) or ropivacaine 0.2% (= group 0.2%) for continuous postoperative interscalene analgesia. Patients were excluded after randomization in case of inadequate placement of the interscalene catheter or accidental catheter removal before end of data assessment. The day before the operation, patients were instructed on how to use the intravenous patient-controlled analgesia (PCA) device with morphine for postoperative rescue analgesia.

All patients received oral premedication with 0.1 mg/kg midazolam one hour before start of the anesthetic procedure. In the induction room, monitoring (electrocardiography, blood oxygen saturation, non-invasive blood pressure) was applied and a 18 gauge intravenous catheter was inserted in the arm not requiring surgery. The interscalene brachial plexus catheter was placed before induction of general anesthesia. Skin disinfection was performed with a two layer application of an alcoholic povidone-iodine solution (Betaseptic®, Mundipharma, Basel, Switzerland). After local anesthetic skin infiltration with lidocaine 1%, the interscalene brachial plexus was identified according to the modified lateral approach (3). The proximal end of the metal inner of the 21-gauge, 70 mm long short bevel needle (Polymedic®, Polyplex, Te me na, 78420 Carnières-sur-Seine, France) was connected to a nerve stimulator (Stimuplex HNS 11®; B. Braun Melsungen AG, Melsungen, Germany), operated by the second person. The initial nerve stimulator setting was 1.4 mA current intensity, 0.1 ms impulse duration and 2 Hz impulse frequency. The final needle position was considered successful when a contraction of the deltoid or proximal triceps muscle was ob-

tained with a minimal current output between 0.3 to 0.4 mA and an impulse duration of 0.1 sec. A 20-gauge interscalene catheter (Polymedic®, Polyplex, Te me na, Bondy, France) was placed with the cannula over needle technique and advanced 3 cm over the tip of the needle. After subcutaneous tunneling through an 18-gauge intravenous catheter for 4 - 5 cm, the interscalene catheter was fixed with transparent adhesive tape and connected to a micro filter (200 nm). At that time, the initial interscalene block was performed preoperatively through the interscalene catheter with 40 ml ropivacaine 0.5 % (200mg). Before general anesthesia, the block was assessed and considered successful, if a sensory block (inability to recognize cold) involving the supraclavicular, axillary, radial and median nerves and a motor block involving the axillary (arm abduction), radial (forearm extension) and musculocutaneous (forearm flexion) nerves was present within 30 min after the administration of the local anesthetic.

General anesthesia was performed with propofol target control infusion (Diprifusor including the Marsh programme for propofol, Graseby pump: Sims Graseby Limited Watford, Herts, United Kingdom). Fentanyl 0.25 mcg/kg and rocuronium 0.9 mg/kg were given to facilitate endotracheal intubation. Rocuronium supplementation was given as necessary. After induction of general anesthesia, all patients received 1 g acetaminophen intravenously, that was repeated every 6 hours until the end of the study. No additional drug was administered through the interscalene catheter during the operative procedure. In all patients an open rotator cuff repair was performed by the same surgeon, with or without tenotomy of the biceps muscle, but without transfer of the latissimus dorsi muscle.

At the end of surgery, patients were extubated and transferred to the post anesthesia recovery unit. Patients were connected to the intravenous PCA-device filled with morphine 1 mg/ml for rescue analgesia. Initial setting of the device was: 2 ml bolus and lock-out time of 10 min without basal infusion. Four hours after the initial interscalene bolus ( $=T_0$ ), continuous infusion through the interscalene catheter was started for 48h (until  $T_{48}$ ) with an infusion rate of 14 ml/h in both groups. The pump and syringe containing either ropivacaine 0.3% or ropivacaine 0.2% were prepared by our pharmacist. The syringes of both groups were identical and neither the patient, the attending

anesthesiologist nor the study nurse could identify patients' group assignment. When patients fulfilled the criteria of the modified Aldrete score (4) they were transferred to the ward.

The following parameters were assessed in all patients by a study nurse blinded to the study drug concentration: Total postoperative intravenous morphine consumption through the PCA-device separately for the time periods  $T_0 - T_{24}$  and  $T_{24} - T_{48}$ ; the time to first intravenous morphine bolus through the PCA-device; postoperative pain intensity in the operated shoulder at rest and with motion by the means of a visual analog scale ranging from 0 (no pain) to 100 (worst pain imaginable) every 8 hours postoperatively until  $T_{48}$  and motion was defined as passive inward and outward rotation of the arm and passive elbow flexion, guided by a physiotherapist. Hand grip strength was measured in the hand of the operated arm by means of a standard electronic pressure sensor and a soft rubber bulb, "the bulb grip device" <sup>2</sup> [see appendix 1]. Measurements were performed preoperatively, at  $T_{24}$ ,  $T_{48}$  and 6h after the end of continuous ropivacaine infusion ( $=T_{54}$ ). Motor block (normal, weakened or no motor function) in the hand of the operated arm was assessed at  $T_{24}$ ,  $T_{48}$  and  $T_{54}$  by asking the patient to adduct the thumb, to flex or to extend the fingers testing the function of the ulnar, median and the radial nerve. The presence of paresthesias [Are paresthesias assumed to be sensory deficits from the block or a neurologic complication (or either)? Please clarify] in the tip of the fingers of the operated arm was recorded at  $T_{24}$ ,  $T_{48}$  (assumed to be sensory deficits from the block at these time points) and  $T_{54}$ . (defined as neurologic complication at this time point) Sleep quality was assessed by patient awakening during the first postoperative night. Only patient awakening because of pain and asking for supplementary analgesia was recorded. Other disturbances interfering with sleep were not considered. Side effects such as nausea, vomiting, pruritus, hoarseness and Horner's syndrome were noted. Patients were interviewed by phone call one month later about the presence of paresthesia or any other sensory or motor deficit.

## **Statistical analysis**

Based on our previous experience, using patient controlled interscalene analgesia with ropivacaine 0.2%, interindividual variation of postoperative intravenous morphine consumption after open

rotator cuff repair is about 50%. A 35% reduction of morphine consumption during the first 24h in patients receiving ropivacaine 0.3% was considered significant. Based on these data, a power analysis indicated that a sample size of 32 patients per group will be sufficient to have an 80% power at the 95% significance level. To increase the power we decided to include 40 patients per group.

Demographic data and were compared with the Mann-Whitney test. VAS values, morphine consumption and muscle strength were analyzed with the Mann-Whitney test with Bonferroni correction for multiple repeated measurements. Side-effects, the incidence of paresthesias and motor block were analyzed with the Chi Square test. Results are expressed as mean  $\pm$  SD if not otherwise specified. For all determinations a  $P < 0.05$  was considered significant.



## Results

Eighty-two patients were randomized (41 in each group). In both groups one interscalene catheter was accidentally removed at 20 and 32 hours postoperatively, respectively. Altogether 40 patients in each group completed the study and their data have been analyzed. A patient flow diagram according to the CONSORT statement (5) is presented in figure 1. There was no difference between the groups regarding demographic patient data and data about the operative procedure (table 1). All the continuous ropivacaine infusions were maintained over 48 hours at a constant rate. The total amount of ropivacaine infused during the study was 2016 mg and 1344 mg in the group 0.3% and group 0.2%, respectively.

No patient needed supplementary analgesics during surgery in either group. Total intravenous morphine consumption from  $T_0 - T_{24}$  and  $T_{24} - T_{48}$  was significantly reduced in group 0.3% ( $7 \pm 7$  mg and  $4 \pm 4$  mg, respectively) compared to group 0.2% ( $14 \pm 9$  mg and  $16 \pm 17$  mg, respectively). In the group 0.3%, the first morphine bolus was required at  $20 \pm 9$  (range: 8 - 36) hours postoperatively. This was significantly later than in the group 0.2%, where patients demanded the first morphine bolus  $8 \pm 2$  (range: 1 - 11) hours postoperatively ( $p < 0.02$ ).

Pain at rest as well as pain with motion was not different between the two groups throughout the study. The relative decrease of the strength at  $T_{24}$ ,  $T_{48}$  and  $T_{54}$ , was similar between the two groups.

There was no statistically significant difference in the hand grip strength between the groups at  $T_{24}$ ,  $T_{48}$  and  $T_{54}$  compared with the preoperative values.

At  $T_{48}$  significantly more patients in the group 0.3% had weakened thumb adduction and weakened flexion of the 2<sup>nd</sup> and 3<sup>rd</sup> fingers (table 2). All other measurements showed no difference between the groups.

The incidence of postoperative paresthesias was similar between the two groups (table 4). The number of patients awakened during the first preoperative night because of pain was significantly higher (27%) in the 0.2% group (95 CI 13.6 – 41.4%) than in the 0.3% group (5%) (95 CI -1.7 –

11.7%). The occurrence of side effects (9 in the group 0.3% versus 8 in the group 0.2%) was similar between the groups. At one month no patient complained of residual paresthesias or the occurrence of new sensory or motor deficit.

Figure 1: Patient flow diagram

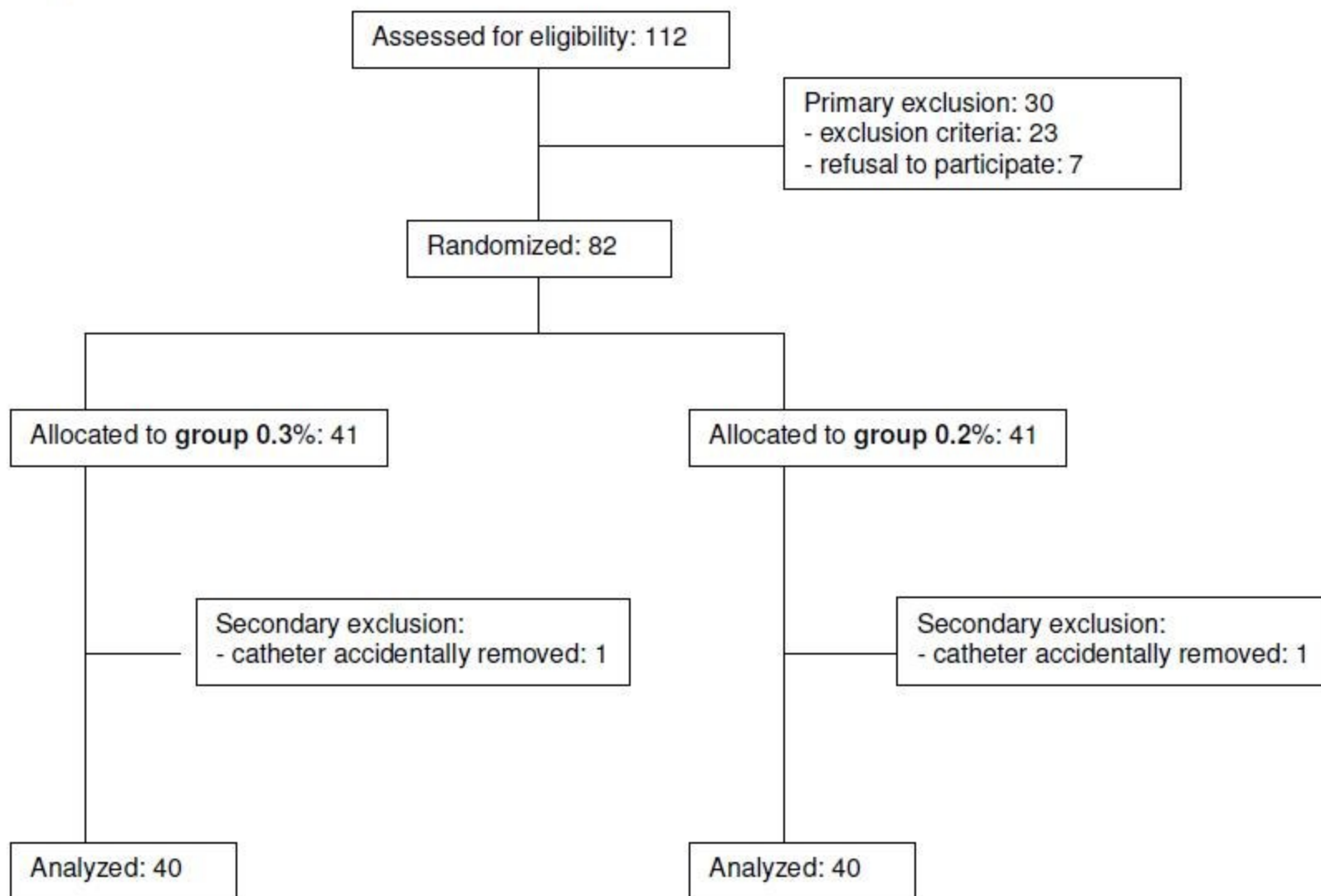


Table 1: Demographic and surgical data

|                            | group 0.2%<br>(n = 40) | group 0.3%<br>(n = 40) |
|----------------------------|------------------------|------------------------|
| Gender (female/male)       | 8 / 32                 | 10 / 30                |
| Age (years)                | 38 ( $\pm$ 15)         | 41 ( $\pm$ 14)         |
| Height (cm)                | 175 ( $\pm$ 7)         | 175 ( $\pm$ 9)         |
| Weight (kg)                | 73 ( $\pm$ 11)         | 78 ( $\pm$ 16)         |
| Operated side (right/left) | 16 / 24                | 14 / 26                |
| Duration of surgery (min)  | 101 ( $\pm$ 30)        | 99 ( $\pm$ 34)         |

There were no significant differences between groups.

**Table 2: Incidence of postoperative paresthesia in the fingers**

| Postoperative time (hours) | finger        | Ropivacaine 0.2% group | Ropivacaine 0.3% group |
|----------------------------|---------------|------------------------|------------------------|
| T <sub>24</sub>            | Dig I (thumb) | 95                     | 90                     |
|                            | Dig II        | 75                     | 75                     |
|                            | Dig III       | 55                     | 45                     |
|                            | Dig IV        | 30                     | 35                     |
|                            | Dig V         | 20                     | 20                     |
| T <sub>48</sub>            | Dig I (thumb) | 65                     | 60                     |
|                            | Dig II        | 45                     | 50                     |
|                            | Dig III       | 35                     | 15                     |
|                            | Dig IV        | 10                     | 10                     |
|                            | Dig V         | 5                      | 5                      |
| T <sub>56</sub>            | Dig I (thumb) | 25                     | 35                     |
|                            | Dig II        | 0                      | 15                     |
|                            | Dig III       | 0                      | 0                      |
|                            | Dig IV        | 5                      | 0                      |
|                            | Dig V         | 5                      | 0                      |

Data are expressed in %

T<sub>24</sub> = 24 hours postoperatively

T<sub>48</sub> = 48 hours postoperatively

There were no significant differences between groups

## Discussion

This study demonstrated that after open rotator cuff repair continuous interscalene analgesia with ropivacaine 0.3% compared to ropivacaine 0.2% provided a significant reduction of morphine consumption and a better sleep quality for the first postoperative night without increasing the intensity of motor block. The only significant difference was weakened thumb adduction and flexion of the 2<sup>nd</sup> and 3<sup>rd</sup> fingers at 48 postoperative hours in the 0.3 ropivacaine group.

The effects of volume and concentration of local anesthetics for continuous central or perineural analgesia are still a matter of controversy. Clinical studies have shown conflicting results as to whether similar results can be obtained by increasing either the volume or the concentration without taking into account the surgeon and the type of surgery (6,7). To avoid the bias of the type of surgery we decided to include only one type of surgery, open rotator cuff repair, a moderate to severely painful surgery (8) performed by single surgeon. – A large initial bolus (40 ml) was chosen to provide a complete interscalene block making supplementary application of analgesics unnecessary during surgery. To avoid the possible confounding factor induced by the patient (use of PCA pump) a continuous infusion of ropivacaine without the option of patient controlled doses was chosen for this study, despite evidence that patient controlled doses improve analgesia for this type of surgery (9). Moreover, fixed-rate infusion is the optimal way to compare different local anesthetic concentration. The rate of infusion of 14 mL/h was chosen according to our previous experiences in this surgical context, taking into account the basal rate and the average number of demanded doses (2).

The hand grasp was chosen to assess motor function since this is the most reliable way to assess this parameter after rotator cuff repair. Hand grasp depends upon both median and ulnar functions and although ulnar function is likely to be less affected with interscalene analgesia, this test remains clinically valid since hand weakness and paresthesia and dysesthesia in the fingers are the symptoms that generate patient complaints. In our data, the hand grasp was not different between groups at any time, despite the weakened thumb adduction and finger flexion in the 0.3 % group observed at 48 h. Although this difference was statistically significant, it was likely too small to in-

fluence the overall strength of the hand grasp. Ropivacaine 0.2% was selected as “control” group since this concentration was shown, compared to bupivacaine 0.15% to provide similar postoperative analgesia and better preservation of strength in the hand and less paresthesia in the fingers (2).

Several studies have investigated the role of volume and concentration after shoulder surgery, but all have involved patient-controlled boluses, complicating a direct comparison with our results. Ilfeld et al(10) compared ropivacaine 0.2 % with a basal rate of 8 mL/h and a 2 mL patient-controlled bolus available each hour to a basal rate of 4 mL/h and 6 mL bolus dose after moderately painful surgery. The authors found that decreasing the basal rate from 8 to 4 mL/h provided similar analgesia, but increased the incidence of breakthrough pain, sleep disturbance and was associated with a lower patient satisfaction. This study emphasizes the importance of volume in the context of shoulder surgery, in agreement with our work where multiple nerves (suprascapular, axillary and supraclavicular) need to be blocked to provide analgesia after open shoulder surgery (11), making volume of local anesthetic a critical issue.

In this study we showed that sleep quality during the first postoperative night was significantly better in the 0.3% ropivacaine group. This is most likely explained by the smoother transition provided by 0.3% ropivacaine when the initial block performed with 0.5 % ropivacaine resolved. This was also shown by Ilfeld et al(10,12) who observed that patients receiving a lower basal infusion through an interscalene catheter experienced a higher incidence of sleep disturbances and breakthrough pain.

The absence of significant difference between the 2 groups concerning morphine induced side-effects can be explained by first, the relatively low consumption of morphine in both groups making the occurrence of side-effect less likely(13). Second, the study was not powered to assess this outcome making a type I error possible.

At 1 month no patient in either group had persistent paresthesias / dysesthesias or the appearance of new sensori-motor deficit, this is in accordance with previous results (3).

In conclusion this study showed that the application of 0.3% ropivacaine compared to 0.2% after open rotator cuff repair reduced morphine consumption, improved the quality of the first postoperative night without increasing the intensity of motor block assessed by hand grasp or side-effects. The results of this investigation suggest that the use of 0.3% ropivacaine through an interscalene catheter during the first 24 h after this surgery may be beneficial for the patient.



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## Appendix 1:

### Description of the hand grip strength measurement

Hand strength was measured by means of a soft rubber bulb, the “bulb grip device”, connected to an electronic pressure transducer (Abbott Critical Care Systems, Abbott, Ireland). The bulb could be held in the hand and squeezed comfortably and was filled with water to offer resistance. The rubber bulb is oval-shaped, as in common use for inflating the pneumatic cuff of a conventional sphygmomanometer. The inlet to the bulb was sealed with a plug after being filled with water. The hydrostatic pressure, which increased on being squeezed, was measured with the pressure transducer connected to the bulb outlet. The transducer delivered an analog electrical signal, directly proportional to the pressure. The pressure transducer was of the electrical resistance type, using a Wheatstone bridge circuit. The bridge was supplied from a 5V stabilized DC source and its output amplified by means of a DC amplifier (3100) before being led to a chart recorder (Watanabet Type WX 441; Watanabe Instrument Corp., Tokyo, Japan) adjusted to 0.1 V/cm sensitivity and set to a sweep rate of 1 cm/s. The system was calibrated by use of a Bourdon-type manometer with a range of 0 to 760 mm Hg that allowed pressure to be read from a scale, graduated in steps of 10 mm Hg, simultaneously. For the purpose of calibration, an external source of pressure that could be adjusted by means of a valve was also connected to the system. The pressure was adjusted in steps of approximately 50 mm Hg from 0 to 650 mm Hg, and the output voltage was recorded. The output signal exhibited a linear relationship of 729 mm Hg/V, or 72.9 mm Hg/cm on the chart recorder. Analysis of four calibration sequences showed a linear regression coefficient of 0.996 with a standard deviation of 617.7 mm Hg. The sensitivity of the device was mainly determined by the chart recorder, which could easily be read to within 61mm (corresponding to 67mm Hg). Because the grip strength is dependent on the position of the limbs, the control measurement (preoperative value) was taken in the postoperative position. All patients were able to use the device. The measurement was repeated at  $T_{24}$ ,  $T_{48}$  and  $T_{54}$ . Each measurement was repeated three times and the one with the highest reading chosen.

## Figure legends

Figure 1: Patient flow diagram

Study design according to the CONSORT statement (6)